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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,452	05/04/2001	Michael Lassner	02-104910US	8657

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MAXYGEN, INC.  
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RED WOOD CITY, CA 94063

EXAMINER
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LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/19/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/849,452

Applicant(s)

LASSNER ET AL.

Examiner

David A Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-132 is/are pending in the application.
- 4a) Of the above claim(s) 1-93 and 105-127 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 94-104 and 128-132 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group VIII in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the claims of the instant application can be examined without undue burden. This is not found persuasive because the different Groups belong to different classes and subclasses in many instances. In those instances where the classes and subclasses overlap, the non-patent literature search that would be required for each of the groups is not co-extensive. Groups I and III-IX have been found to be unrelated because the methods require different procedural steps, and these different steps would require different searches, thus the search of more than one group as set forth in the previous Office Action would be burdensome. Groups I and II are related as process of making and product made, and Group II can be made by a materially different process, therefore these inventions also require searches that would be burdensome because they would not be co-extensive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-93 and 105-127 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claims 94-104 and newly added claims 128-132 are ready for examination in the instant application.

***Information Disclosure Statement***

The information disclosure statement filed December 11, 2001 (Paper No. 5) fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because several of the references as listed have not been supplied, specifically Cite No. AC, AF, AJ, AL, BD, BG and CE. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

The information disclosure statement (IDS) submitted on February 15, 2002 (Paper No.6) has been considered by the examiner.

***Priority***

Applicant's claim for domestic priority to non-provisional application 60/202233 under 35 U.S.C. 119(e) is acknowledged.

***Sequence Compliance***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences were set forth that lack sequence identifiers, no computer readable format (CRF) was

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filed, no paper sequence was filed and no attorney statement was filed. These sequences include those listed on page 15, lines 20 and 21.

Applicants are required to comply with the requirements of 37 CFR 1.821-1.825. Any response to this Office Action that fails to meet all of these requirements will be considered non-responsive. Specifically, applicant must submit a CRF and paper copy of the sequences as indicated along with a letter saying that the paper copy and CRF are the same, and that no new matter has been entered into the specification. Applicant must also amend the specification to identify the sequences with SEQ ID NOS. A Notice to Comply has been attached to the Office Action.

The nature of the non-compliance with the requirements of 37 CFR 1.821-1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

### ***Claim Objections***

Claims 94, 97 and 99 are objected to because of the following informalities: claims 94 and 97 contain an abbreviated name that should be defined in its first appearance in the claims (“R gene” and “Avr gene”, respectively); “acquired” is misspelled in claim 99. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 94, 96, 97, 99-102 and 128-131 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Any protein can act as a reporter, for example by screening for a particular phenotype or examining isolates for the expression of the protein (e.g., western blot). R-genes are known to elicit the expression of certain genes in response to a pathogen, therefore those naturally occurring genes can be used as reporters. As such, any naturally occurring protein can comprise a bio-detector as claimed in the instant application, thus the "hand of man" is absent from the invention as claimed. Use of the term "recombinant bio-detector" would be remedial.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 94-104 and 128-132 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 94 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. The claim recites the phrase "capable of activation by at least one elicitor", but it is unclear if it is the R-gene or the R-gene product that is being activated by the elicitor.

Claim 95 (and all dependent claims) is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. It is unclear what a "specified characteristic" includes and excludes. The specification teaches

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enhanced resistance/response of plants to pathogens/environmental stressors. Is this the specified characteristic, or is there another specified characteristic? Who specifies the characteristic, and what are the criteria under which the characteristic is specified?

Claims 96 and 97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. These claims recite the terminology “designated elicitor”, but it is not clear where the elicitor is designated, or pointed out. Replacing “designated” with “corresponding” would be remedial.

Claim 99 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim recites the phrase “promoter derived from a gene”. Is the promoter a gene, or a mutated gene that now has promoter activity? Is the promoter one that is primarily associated with a particular gene? Stating that “the promoter comprises a systemic acquired resistance (SAR) pathway promoter” would be remedial.

The term "environmentally relevant ligand" in claims 128-132 is a relative term which renders the claim indefinite. The term "environmentally relevant ligand" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. To what environment is the ligand relevant? This is especially confusing in claim 132, where it appears a human or animal pathogen is an “environmentally relevant ligand” for plants.

Claim 130 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. The claim recites the phrase “pathogen derived product”. Is the product a mutated pathogen, a product produced by

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the pathogen, a chemically modified product from a pathogen, etc.? Stating that the product is produced by a crop pathogen would be remedial.

Claim 130 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. The claim recites the phrase "has not been ascribed elicitor function". The metes and bounds of the claim are unclear because it is unclear how one can construct a bio-detector for an elicitor if it has not been shown to be an elicitor for an R-gene; for example, how can one know what promoter to use for the expression of the reporter gene? Also, it is unclear if the elicitor is a known elicitor that has an unknown mechanism, or if it is unknown whether or not the molecule is an elicitor?

***Allowable Subject Matter***

No claims are allowable.

Claims 98, 103 and 104 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (703) 305-1998. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson  
November 18, 2002

  
PATENT EXAMINER

<b>Notice to Comply</b>	Application No. <b>09/849452</b>	Applicant(s) <b>Lassner <i>et al.</i></b>	
	Examiner <b>David A. Lambertson</b>	Art Unit <b>1636</b>	

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS  
CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE  
DISCLOSURES**

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: Sequences in application not in Sequence Compliance (see attached Office Action).

**Applicant Must Provide:**

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923

For CRF Submission Help, call (703) 308-4212

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